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APLICATION NUMBER	THE PTO DATE	NAME OF INVENTOR
09-678,303	10/03/2000	Louis-Philippe Vezina

ATTORNEY OR AGENT NUMBER	REGISTRATION NUMBER
14149-4 "US" FC:ntb	5731

20988            7590            12/18/2002  
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ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/18/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/678,303	VEZINA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b)

#### Status

- 1) Responsive to communication(s) filed on 12 October 2002.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5,9 and 10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Restriction election & Status of the Claims***

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 11, filed 21 October 2002. Applicant elects Group I, claims 1-5 with traverse, stating that the promoter claimed in Group I cannot be used for any other purpose than that of being a promoter and therefore restriction is improper. Applicant's traversal is unpersuasive for the following reasons-- the product as claimed can be used in a materially different process of using that product, that of being used as DNA hybridization probe. Therefore, restriction is proper and is made final.
2. New claims 9 and 10 have been added by Applicant, in an Amendment, paper No. 13, dated 15 November 2002, and are grouped with Group I claims.
3. Claims 1-10 are pending. Claims 6-8 are nonelected. Claims 1-5 and 9-10 are examined in the instant application. This restriction is made FINAL.

### ***Specification***

4. The first line of the specification is objected to because it recites the serial number of the present application, while stating that this application is a continuation of the same. Correction is required.

In addition, note that Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

***Sequence Listing***

5. Applicant's CRF and paper sequence listing have been entered.

***Claim Rejections - 35 USC § 112, second paragraph***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 1, 2 and 4, and claims 3,5, 9 and 10 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1

- "gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may recite the various components of the "gene" desired. All subsequent recitations are also rejected.
- "functional fragments" is indefinite because the function is not described;
- "derivatives thereof" is unclear because it is not clear what of the starting material is retained and what is left behind.
- "said gene" lacks antecedent basis.

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- “adapted” is unclear because it implies that the promoter has been modified, but no modification is described.
- “operably located” is indefinite. Suggested language here is deleting “adapted to be” and replacing “located with respect” with “linked” so that this reads: “said promoter is operably linked to said”.

In claim 2, “modulated ...by presence or absence of light” is confusing because the would encompass all situations. Therefore , t he inclusion of this phrase fails to further limit the subject matter of claim 1.

In claim 4, “said organism” lacks antecedent basis.

Clarification and/or correction are required.

***Claim Rejections - 35 USC § 112, first paragraph***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-5 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

10. The Declaration of Dr. Marc-Andre Daoust, an inventor, dated 21 February 2001, is acknowledged. This Declaration gives experimental information and data about Gus

reporter gene expression in alfalfa cell lines and in tobacco using a particle gun delivery system, citing these results as being “unexpected results”.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

*The nature of the invention.* The claims are drawn to promoters useful for expressing foreign genes in transgenic organisms, including where the organisms are plants, including dicots, monocots, or gymnosperms, expression vectors comprising these promoters, and genetically transformed plant cells or plants. And further drawn to DNA SEQ ID NO: 1-3 and functional fragments or derivatives thereof. And further drawn to modulation of these promoters by the presence or absence of light. And further to methods of regulating expression of foreign genes in transgenic organisms using these promoters.

*The state of the art, and the predictability thereof.* The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03). The state of the art is such that the skilled person can construct vectors by putting pieces of DNA together, and can introduce DNA into plant cells. However the skilled person would not expect to take a DNA sequence defined only by a given DNA SEQ ID NO., or a functional fragment, or derivative thereof, and be able to construct a functional expression vector from any of these materials.

*The amount of guidance given, and the presence of working examples.*

Applicant gives no guidance for the use of the promoter sequences of the SEQ ID NO: , or the functional fragments, or derivatives thereof—how to construct expression vectors, how to configure the various nucleic acids with respect to one another, in what proximity, in what orientation, for them to function in accord with the claimed invention.

The Declaration of Dr. Marc-Andre Daoust gives experimental information and data relating to Gus reporter gene expression in alfalfa cell lines and in tobacco using a particle gun delivery system. However, the starting materials for the experiments described in the Declaration-- the specific DNA delivered, the specifics of the DNA constructs, what sequences and genes are involved, whether an expression cassette or vector is involved, are not described other than citing “the P960 deletion”. No information is given on the relationship of the specifics of the Declaration to the claimed invention.

*The amount of experimentation necessary.* Guidance is not given about what parameters, conditions and variables would need to be evaluated in order for inoperable embodiments to be eliminated. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

*The breadth of the claims.* The claims are drawn to promoters useful for expressing foreign genes in transgenic organisms, including where the organisms are plants, including dicots, monocots, or gymnosperms, expression vectors comprising these promoters, and genetically transformed plant cells or plants. And further drawn to

DNA SEQ ID NO: 1-3 and functional fragments or derivatives thereof. And further drawn to modulation of these promoters by the presence or absence of light. And further to methods of regulating expression of foreign genes in transgenic organisms using these promoters.

Even if Applicant were enabled for a promoter of SEQ ID NO: 1-3 operably linked to a Gus reporter gene expressing in an alfalfa cell line, Applicant is not be enabled for all plant cells, or for the broad scope of the claims. This is because using a promoter isolated from one species of plant would produce unpredictable results when said promoter is used to specify expression of a gene in another species of plant. Oommenn et al (1994, The Plant Cell 6:1789-1803) teach that the alfalfa isoflavone reductase promoter exhibits a different expression pattern in tobacco as compared to the expression in alfalfa. In tobacco, the alfalfa isoflavone reductase promoter expressed in vegetative tissues and in reproductive organs whereas the same construct only expressed in the root meristem, cortex and nodules of alfalfa plants (abstract). Nor are fragments or "functional fragments" of a promoter predictable as to their expression characteristics. Benfey, et al, US patent 5, 110, 732, showed that various fragments of the CaMV 35S promoter exhibit different expression characteristics in tobacco tissue. That one fragment exhibits selective expression in root tissue and in the radical of the seed; whereas, another fragment exhibits constitutive expression in plant tissue other than root tissue.

In view of the breadth of the claims (any transgenic organism, any plant cell or any plant, including dicots, monocots, or gymnosperms, DNA SEQ ID NO: 1-3,

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functional fragments or derivatives thereof and any selectable marker), the high level of unpredictability in the art, the lack of guidance in the specification, the absence of working examples, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

**Remarks**

11. No claim is allowed.

12. SEQ ID NO: 1, 2, and 3 are free of the prior art.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD  
Patent Examiner  
Art Unit 1638  
December 13, 2002

*Elizabeth F. McElwain*  
ELIZABETH F. MC ELWAIN  
PRIMARY EXAMINER  
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